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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,526	02/21/2002	Jutaro Shudo	TEIK-004	8649

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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

10/080,526

Applicant(s)

SHUDO ET AL.

Examiner

Isis Ghali

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 25-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 37-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicants' declaration, filed 05/06/2002; IDS, filed 06/11/2002; change of address, filed 08/23/2002; IDS, filed 12/02/2002; and election, filed 07/11/2003.

Election/Restrictions

1. Applicant's election of Group I, claims 1-8, 18-24, and 37-40 in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). However, the species election has been **withdrawn**.

2. Claims 25-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups II and III, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Claims 1-24, and 37-40 are included in the prosecution.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 7, 18-22, 24 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,846,559 ('559).

US '559 disclosed a skin patch for delivering a contactant to the human skin for treating medical conditions responsive to contact immunotherapy and the patch is used to enhance the function of immune system in person having states of immune deficiency e.g. AIDS (abstract; col.3, lines 9-11). The contactant is dinitrochlorobenzene, i.e. DNCB (abstract; col.3, lines 28-30). The patch comprises a gel polymer containing the drug and a shroud, the shroud reads on the support claimed by applicants (col.4, lines 27-30; col.5, line 21). The gel polymer is adhesive and comprises: a) DNCB; b) carboxymethyl cellulose, that disclosed by applicants as one of the water soluble gel polymers in their specification paragraph 0022; c) butanol, that disclosed by applicants as one of the water retaining agent in their specification paragraph 0024; and d) water (col.5, lines 57-59; col.6, lines 9-12; col.9, lines 55-56). The gel polymer composition further comprises an organic solvent (col.4, line 5). The amount of DCNB in the gel polymer forms 0.001 to 30% by weight (col.6, lines 16-19).

When the patch is applied to the skin, the solubilized contactant will be released immediately from the patch, and over time additional contactant will be slowly released from the patch to the underlying skin (col.7, lines 40-45).

The limitation of claims 1-4, 7, 18-22 and 24 are met by US '559.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '559.

The teachings of US '559 are discussed under 102 rejection above.

However, the reference does not teach the amount of the water in the composition.

The amount of water in the composition does not impart patentability to the composition, absent evidence to the contrary.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a topical patch comprising gel comprising DNCB, water soluble polymer, water, organic solvent and water retaining agent, as disclosed by US '559, and adjust the amount of water to the needed consistency of the gel, with reasonable expectation of having a patch comprising polymer gel comprising DNCB that can be delivered to the skin of the patient on need in a controlled manner with success.

8. Claims 5, 6, 8-17, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '559 in view of US 5,891,920 ('920).

The teachings of US '559 are discussed under 102 rejection above.

However, the US '559 reference does not teach the amount of the water in the composition, the pH of the gel, or the species of the organic solvents.

US '920 teaches a percutaneously absorbable preparation that have excellent drug releasing properties for a long period, so that the drug can be absorbed into the

circulatory system through the skin in an amount enough to exhibit the objective effects (col.11, lines 59-64). The preparation can be in the form of gel that comprises: a) drug from amount of 0.001 to 20 %; b) water in an amount of at least 55%; c) glycol, that is disclosed by applicant as organic solvent; and d) alcohol, that is disclosed by applicants as water retaining agent (col. 10, lines 32-39). The gel has pH in the range from 4-7 (col.10, lines 40-42).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a topical patch comprising gel comprising DNCB, water-soluble polymer, water, organic solvent and water retaining agent, as disclosed by US '559, and adjust the amount of water and the pH of the gel to the amount disclosed by US '920, and select the organic solvent to be glycol as disclosed by US '920, motivated by the teaching of US '920 that the disclosed percutaneously absorbable preparations have excellent drug releasing properties for a long period, so that the drug can be absorbed into the circulatory system through the skin in an amount enough to exhibit the objective effects, with reasonable expectation of having a patch comprising polymer gel comprising DNCB that can be delivered to the skin of the patient in need at a controlled manner with success.

9. Claims 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '559 in view of US 5,476,664 ('664).

The teachings of US '559 are discussed under 102 rejection above.

However, the US '559 reference does not teach the kit that has plurality of patches in sealed pouches and the instruction for using the kit.

US '664 teaches a kit for delivering medication to the skin, the kit comprises a stack of adhesive patches and instruction sheet (col.15, line 64-67; figure 1). The figure also shows that the patches are individually packaged.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver patches comprising DNCB as disclosed by US '559, and provide the patches in the form of the kit disclosed by US '664 that comprises plurality of patches and instruction for using the kit, motivated by the skill in the art that kits are more convenient to the patient and induce compliance and avoidance of forgetfulness of having refills and the instruction allows for the correct method of use for the patches without over dosage, with reasonable expectation of having the DNCB in kit that delivers the drug to the patients in need at a regular safe manner.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone

Art Unit: 1615

number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

A handwritten signature in cursive script, appearing to read "Isis Ghali".